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EXAMINER	
KIM, YUNSOO	
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Please find below and/or attached an Office communication concerning this application or proceeding.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/714,575
Filing Date: November 14, 2003
Appellant(s): TZANNIS ET AL.

Naishadh N. Desai
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 8/11/08 appealing from the Office action mailed 3/11/08.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The amendment after final rejection filed on 5/9/08 has been entered.

Upon entry of the amendment after final, claims 1-56 and 59-74 are pending.

Claims 1-30 and 60-74 stand withdrawn from the further consideration by Examiner, 37 C.F.R.1.142(b) as being drawn to a nonelected invention.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

Claims 31-56 and 59 rejected under 35. U.S. C 112 first paragraph, as containing subject matter which was not described in the specification, has been withdrawn.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

U.S. Pat. No. 6,267,958	Andya et al.	07-2001

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 31-56 and 59 are rejected under 35 U.S.C. 102 (b) as being anticipated by U.S. Pat. No. 6,267,958 (IDS reference AK, of record).

The '958 patent teaches a stable reconstituted formulation comprising an antibody of about 50 mg/ml, diluent, buffer and sucrose as an excipient (claims 1-8, 47 col. 17, lines 1-40, Table 5-6, in particular).

The '958 patent further teaches the antibody is full length, fragmented (Fab, $F(ab)_2$), murine, chimeric, and CDR grafted as well as humanized (col. 7-8, 10-12). The '968 patent teaches that the antibody is IgE or IgG (e.g. anti-HER2, Examples 1-2) and conjugated (e.g. heteroconjugates, col. 14, lines 18-27).

Moreover, the '958 patent teaches the buffer including phosphate and histidine (col. 14-15 overlapping paragraph) as an excipient, sterile water, bacteriostatic water for injection, or saline as a diluent (col. 9, lines 39-45, col. 17, lines 1-40) and a polysorbate as a surfactant (col. 15, lines 35-60). In addition, the '958 patent further teaches packaging of the composition in vial and syringes (col. 18, lines 24-49).

Claim 59 is included in this rejection as the '958 patent teaches the referenced antibody formulation is 99+% intact (Tables 4-6).

The claimed invention is drawn to a reconstituted antibody formulation comprising an antibody formed from a spray-dried powder and an excipient, and the patentability of the product does not depend on its method of production. Moreover, being a "visually clear reconstituted composition within about 10min" is an inherent property of the antibody composition comprising antibody, histidine and polysorbate. Thus, prior art teachings anticipate the claimed invention.

(10) Response to Argument

Appellants' arguments filed 8/11/08 have been fully considered but they are not persuasive.

At pages 12-13 of the Brief, Appellants traversed the rejection based on that the referenced composition will not inherently become a visually clear reconstituted composition within about 10minutes as claimed. Appellants assert that the '958 patent fails to teach the "spray dried powder".

The claimed invention is drawn to a reconstituted composition comprising an antibody in amount of about 25mg/ml to about 200mg/ml, a diluent and an optional pharmaceutically acceptable excipient and the dependent claims recite various excipients including carbohydrates (sucrose, trehalose), amino acids (histidine) and surfactants (polysorbate).

The referenced antibody formulation comprises an antibody, diluent, buffer, sucrose and polysorabte (claims 1-8, 47 col. 17, lines 1-40, in particular).

Contrary to Appellants' arguments, the claimed antibody composition and the referenced antibody composition are structurally identical. The functional limitation of "being visually clear upon reconstitution within about 10min" is an inherent property of the claimed and the referenced antibody formulations.

Furthermore, at page 13 of the Brief, Appellants use the passage from the '958 patent as a basis that the inherency is not established. Appellants point out that the '958 patent discloses the "time required for reconstitution will depend e.g. on the type of diluent, amount of excipient(s) and protein" (col. 17, lines 23-25 of the '958 patent). However, the specification of the instant application on p. 37-38 (Example 1, Table II) and the page 13 of the Brief showed the reconstitution time of lyophilized formulation (e.g. type disclosed in the '958 patent) is 11 minutes, which is encompassed by the claimed "within **about** 10 minutes. The lyophilized antibody has been reconstituted in 11 minutes in deionized water in the example and the addition of excipient facilitates the reconstitution. Therefore, the functional limitation of "being visually clear upon reconstitution within about 10 minutes" is an inherent property of the claimed and the referenced antibody formulations.

Moreover, Appellants assert that the '958 patent fails to teach every element of the claimed invention, spray-dried powder.

However, the claimed invention is a product claim. The method step, "spray-dried", is incorporated by the product claim. The method step which describes how the antibody was prepared, "spray dried" as recited, does not have any patentable weight unless the method step results in a structurally distinct product. As discussed earlier, the referenced and claimed antibody formulations are identical and the patentability of the product does not depend on its method of production. Thus, prior art teachings anticipate the claimed invention.

11) Related Proceeding(s) Appendix

For the above reasons, it is believed that the rejections should be sustained.
Respectfully submitted,

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